K062040

510(k) Summary

OCT - 3 2006

Manufacturer:	rms Company 8600 Evergreen Boulevard Minneapolis, MN 55433 763-786-1520 – Office 763-783-5073
Submitted By:	Small Bone Innovations James O' Connor 505 Park Avenue, 14th Floor New York, NY 10022 joconnor@totalsmallbone.com 215-428-1791 – Office 212-750-2112 - Fax
Proprietary Name:	SBi Trihedron MTP Hemi Great Toe
Classification name:	Class II, 888.3730 – Prosthesis, Toe, Hemi-, Phalangeal
Common/Usual Name:	Toe joint phalangeal (hemi-toe) polymer prosthesis
Substantial Equivalence:	Documentation is provided which demonstrated the SBi Trihedron MTP Hemi Great Toe to be substantially equivalent to other legally marketed devices.
Device Description:	The SBi Trihedron MTP Hemi Great Toe Implant consists of a single piece cobalt chromium head and stem. The stem of the implant is coated with CPTi coating and is designed to be inserted into the shaft of the proximal phalanx of the great toe in the metatarsophalangeal joint. The head of the implant articulates with distal head of the first metatarsal. The implant is available in several sizes, each of which can be used in right or left feet. A range of trial sizers for each size of implant is available to aid in bone preparation.
Intended Use:	The SBi Trihedron MTP Hemi Great Toe is intended as a resurfacing implant for the metatarso-phalangeal joint for: 1) Arthritic degeneration of the metatarso-phalangeal joint that has resulted in disabling pain, limited motion and loss of normal ambulatory function of the forefoot; 2)Degenerative arthritis; 3)Rheumatoid arthritis; 4)Bunion deformity associated with

	arthritis of the metatarso-phalangeal joint rheumatoid arthritis; 5) correction of functional deformity; 6) revision procedures where other treatments and devices have failed; and 7) treatment of fractures that are unmanageable using other techniques.
Material:	ASTM F-1537 wrought cobalt chromium molybdenum alloy for surgical implants ASTM F-1580 titanium powders for coating of surgical implants

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2006

Small Bone Innovations
% Mr. James O'Conner
505 Park Avenue, 14th Floor
New York, New York 10022

Re: K062040
Trade/Device Name: SBi Trihedron MTP Hemi Great Toe
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: Class II
Product Code: KWD
Dated: July 13, 2006
Received: July 19, 2006

Dear Mr. O'Conner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: SBi Trihedron MTP Hemi Great Toe

Indications for Use:

The SBi Trihedron MTP Hemi Great Toe is intended as a resurfacing implant for the metatarso-phalangeal joint for:

1. Arthritic degeneration of the metatarso-phalangeal joint that has resulted in disabling pain, limited motion and loss of normal ambulatory function of the forefoot.
2. Degenerative arthritis
3. Rheumatoid arthritis
4. Bunion deformity associated with arthritis of the metatarso-phalangeal joint

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bowles for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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